Exhibit 1

Inspections, Compliance, Enforcement, and Criminal Investigations

HeartWare Inc 6/2/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4770

VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

WARNING LETTER
FLA-14-14
June 2, 2014

Mr. Doug E. Godshall
President/ Chief Executive Officer
HeartWare, Incorporated
205 Newbury Street, Suite 101
Framingham, MA 01701

Dear Mr. Godshall:

During an inspection of your firm located at 14400 NW 60th Avenue, Miami Lakes, Florida 33014, on January 13, 2014, through January 24, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the HeartWare Ventricular Assist Device (HVAD) system. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, or to affect the structure or any function of the body.

The inspection revealed that this device is adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice (cGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. A Form FDA 483, Inspectional Observations (FDA 483), was issued to Mr. Robert E. Yocher, Senior Vice President of Regulatory Affairs and Quality, at the close of this inspection (copy enclosed).

We received responses from Mr. Yocher, dated February 14, 2014, and March 11, 2014, concerning our investigator's observations noted on the FDA 483 that was issued to your firm. We address these responses below, in relation to each of the noted violations. We received two additional responses from your firm, dated April 14, 2014, and dated May 14, 2014. We will evaluate these responses along with any other written material provided in response to the violations cited in this Warning Letter. The violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g). For example, your firm's Design Control System Procedure 04300, Rev. 12, dated June 11, 2013, does not require design validation of device labeling (Patient Manual) to ensure that it is properly understood by patients and caregivers.

Your firm's responses are not adequate. Your firm provided documentation of updated procedures and training modules. However, your firm did not indicate what retrospective activities will be conducted to ensure that design validation for the HVAD system was adequately handled.

2. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a). For example:

a) Your firm received at least 27 complaints between February 2010 and November 2013, including reports of 2 deaths and 4 serious injuries, of HVAD controller failure for which ESD was determined to be the most likely root cause. Your firm initiated corrective actions including labeling changes to the Patient Manual released to new patients in July 2013 and a Safety Alert Letter to doctors in May 2013. However, your firm failed to verify or validate the effectiveness of these corrective actions.

b) Your firm did not adequately implement its CAPA Procedure 05403, Rev. 12, dated June 6, 2013, in response to premature battery failure issues related to at least 238 complaints and MDR events.

c) Your firm did not adequately implement its CAPA Procedure 05403, Rev. 12, dated June 6, 2013, in that your firm did not complete rework of controller inventory with updated ESD shield design or complete any type of field action after release of the updated ESD shield design.

d) Your firm initiated field actions in response to complaints regarding loose driveline connectors. However, corrective actions were not effective in that driveline connectors again came loose.

Your firm's responses are not adequate. Your firm initiated changes to procedures and training of personnel. However, your firm did not indicate what actions will be taken to assess the effectiveness of the corrections and whether retrospective assessments will be performed to determine if the root causes were adequately addressed by the corrections.

3. Failure to maintain a record of the investigation by the formally designated unit when an investigation is made under this section, as required by 21 CFR 820.198(e). For example, your firm's Product Investigation Report (PIR) Work Instruction (WI 00305) requires documentation of likely or potential root cause. However, your firm did not document the likely or potential root cause or document an attempt to obtain the complete nature and details of at least 10 complaints which were submitted to FDA as MDR events.

The adequacy of your firm's responses cannot be determined at this time. Your firm indicated that it will revise its procedures, perform training, and conduct a retrospective review of all complaints through completion of gap assessments. However, without evidence of implementation of these activities, FDA cannot determine adequacy.

4. Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i). For example, your firm did not validate software used with the **(b)(4)** tester prior to implementation of the new test, as required by SOP00090, "**(b)(4)**." According to Section 2 of SOP00090, this procedure applies to "any software used to automate device design, testing, component acceptance […] or to automate any other aspect of the quality system." Section 6 of this SOP requires software validation. The software for the **(b)(4)** tester was changed as part of a corrective action to address premature battery failure issues. The new test was implemented on July 23, 2013, before the modified software was validated in September 2013. This change was related to 238 complaints and 119 MDR events.

The adequacy of your firm's responses cannot be determined at this time. Your firm indicated that it will revise its procedures, perform training, and retrospectively conduct software validation of the battery testers. However, without evidence of implementation of these activities, FDA cannot determine adequacy.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies may be advisedof the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Furthermore, requests for Certificates to Foreign Governments will not be granted until the violations related to the subject device have been corrected.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps you have taken to correct the noted violations, as well as an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions you have taken. If your planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of these activities. If corrections and/or corrective actions cannot be completed within 15 business days, state the reason for the delay and the time within which these activities will be completed. Your response should be comprehensive and address all violations included in this Warning Letter.

Your response should be sent to: Erica M. Katherine, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751. Refer to Unique Identification Number CMS423678 when replying. If you have any questions about the contents of this letter please contact Ms. Katherine at (407) 475-4731.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Form FDA 483, Inspectional Observations, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,
/S/
Elizabeth W. Ormond
Acting Director, Florida District

Cc: via UPS next day air, with delivery confirmation
Mr. Ramon Paz
Vice President of Quality Assurance
HeartWare, Inc.
14400 NW 60th Avenue
Miami Lakes, Florida 33014

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